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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Madar, et al.

Serial No.: 10/788,993

Filed: February 27, 2004

Title: PHARMACEUTICAL  
COMPOSITIONS AS INHIBITORS OF  
DIPEPTIDYL PEPTIDASE-IV (DDP-IV)

Case No.: 6979USP1

Group Art No.: 1614

Examiner: (not yet assigned)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450 on:

Date of Deposit: June 10, 2004

Tanya Parent 6/10/04  
Tanya Parent Date

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed, to the knowledge of the undersigned, before the mailing date of a first Office Action on the merits. Applicants respectfully petition and request that the Examiner consider the listed documents and evidence such consideration by making appropriate notations on the attached form. Copies of the listed documents are attached.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

The Commissioner is authorized to charge our Deposit Account any additional fees (or credit any over payments) that may be required under 37 C.F.R. §§ 1.16 and 1.17 in association with this communication for which full payment has not been tendered.

Respectfully submitted,  
Madar, et al.

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**TRANSMITTAL LETTER**

Dear Sir:

Enclosed herewith for the patent application identified above entitled PHARMACEUTICAL COMPOSITIONS AS INHIBITORS OF DIPEPTIDYL PEPTIDASE-IV (DDP-IV) are the following:

1. Information Disclosure Statement;
2. Form PTO 1449, in duplicate;
3. References as cited on PTO 1449 (15 references); and
4. Return Receipt Postcard.

The Commissioner is hereby authorized to charge any additional Filing Fees required under 37 CFR §1.16, as well as any patent application processing fees under 37 CFR §1.17 associated with this communication for which full payment had not been tendered, to Deposit Account No. 01-0025.

Respectfully submitted,  
Madar, et al.

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DATE: June 10, 2004

SHEET 1\_ of 1\_

Form PTO-1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Modified) PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

6979USP1

SERIAL NO.

10/788,993

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT

D. J. Madar, et al.

FILING DATE

February 27, 2004

GROUP

1614

(37 CFR 1.98 (b))

## U.S. PATENT DOCUMENTS

Examiner Initials		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
	A1	5,691,356	11/25/1997	Kimball, Spencer D.			
	A2	6,011,155	01/04/02	Villhauer			
	A3	6,172,081	1/9/2001	Damon, Robert			
	A4	6,395,767	05/28/02	Robl, et al.			

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLIC- ATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS- LATION
	B1	01/34594	17.05.2001	WO			YES NO
	B2	01/68603	20.09.2001	WO			
	B3	01/96295	20.12.01	WO			
	B4	93/01167	21.01.93	WO			
	B5	04/016587	26.02.04	WO (translation included)			X

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

C1	Coutts, Simon J., "Structure-Activity Relationships of Boronic Acid Inhibitors of Dipeptidyl Peptidase IV. 1. Variation of the P <sub>2</sub> Position of X <sub>aa</sub> -boroPro Dipeptides
C2	Ahren, B., "Inhibition of Dipeptidyl Peptidase IV Improves Metabolic Control over a 4-Week Study Period in Type 2 Diabetes", Diabetes Care, Vol. 25, No. 5, May 2002, pp 869-875
C3	Deacon, C. F., "Dipeptidyl Peptidase IV Inhibition Potentiates the Insulinotropic Effect of Glucagon-Like Peptide 1 in the Anesthetized Pig", Diabetes, Vol. 47, May 1998, pp 764-769
C4	Ohnuma, K., "Soluble CD26/Dipeptidyl Peptidase IV Induces T Cell Proliferation through CD86 Up-Regulation on APCs <sup>1</sup> ", J. of Immunology, Vol. 167, No. 12, 2001, pp 6745-6755
C5	Villhauer, Edwin B., "1-3-Hydroxy-1-adamantyl) amino] acetyl]-2-cyano-(S)-pyrrolidine: A Potent, Selective, and Orally Bioavailable Dipeptidyl Peptidase IV Inhibitor with Antihyperglycemic Properties, " J. Med. Chem. 2003, Vol. 46, pp 2774-2789
C6	Hughes, T.E., "1-2-5 Cyanopyridin-2-yl) amino ethyl amino acetyl-2-cyano-(S) pyrrolidine), a Slow Binding Inhibitor of Dipeptidyl Peptidase IV", Biochemistry 1999, Vol. 38, pp 11597-11603

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Form PTO-1449)

x Did not receive